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**Notice of Allowability**

Application No.

10/728,275

Examiner

Hope A. Robinson

Applicant(s)

VARADHACHARY ET AL.

Art Unit

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/2/01.
2. ☒ The allowed claim(s) is/are 1,3-13 and 21-31.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached.
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 9/1/05.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

**EXAMINER'S AMENDMENT**

***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

***Withdrawn Objections/Rejections***2. (a) Previous objection to the

specification is withdrawn by virtue of submission of an amendment and applicant's arguments presented on page 6 of the response filed June 21, 2005.

(b) Previous rejections under 35 U.S.C. 112, second paragraph are withdrawn by virtue of submission of the amendment filed June 21, 2005.

(c) Previous rejections under 35 U.S.C. 102 and 103 are withdrawn by virtue of applicant's amendment filed on June 21, 2005 and the below examiner's amendment.

3. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Authorization of this Examiner's amendment was given in a telephone interview with Ms. Melissa W. Acosta on September 2, 2005.

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5. The claims have been amended as follows:

Please cancel claims 14-16, 18 and 20 without prejudice.

- (a) Claim 1 (Currently Amended) A method of treating [[a cardiovascular disease]] atherosclerosis or vascular inflammation comprising: [[the step of parenterally or]] orally administering to a subject an effective amount of lactoferrin; [[composition]] and administering an antacid in conjunction with said lactoferrin [[wherein the cardiovascular disease is atherosclerosis or vascular inflammation]].
- (b) Claim 3 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces levels of circulating total cholesterol, low density lipoproteins (LDL), very low density lipoproteins (VLDL), or triglycerides in said subject.
- (c) Claim 4 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] increases the levels of circulating high density lipoproteins (HDL) in said subject.
- (d) Claim 5 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces the levels of vascular inflammation in said subject.
- (e) Claim 6 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces circulating C-reactive protein (CRP) in said subject.
- (f) Claim 7 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces the proliferation of vascular smooth muscle cells in said subject.
- (g) Claim 8 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces vascular spasm or vascular hyper-reactivity in said subject.

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- (h) Claim 9 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] promotes endothelial integrity or healing in said subject.
- (i) Claim 10 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] is dispersed in a pharmaceutically acceptable carrier.
- (j) Claim 26 (Currently Amended) The method of claim 1, wherein said lactoferrin [[composition]] reduces the production or activity of pro-inflammatory cytokines.
- (k) Claim 27 (Currently Amended) The method of claim 1, further comprising administering a lactoferrin [[composition]] in combination with an anti-cholesterol agent or an anti-inflammatory agent.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled AComments on Statement of Reasons for Allowance.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

*HR*  
*9/2/05*

*Kathleen M. Kerr*  
**KATHLEEN M. KERR, PH.D.**  
**SUPERVISORY PATENT EXAMINER**